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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/437,912	11/09/1999	KEITH R. MCCRAE	6056-257	8628

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EXAMINER

ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 05/02/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/437,912

Applicant(s)

McCrae

Examiner

Hope Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 24, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 8, 9, 16, 19, 22, and 30-49 is/are pending in the application.
- 4a) Of the above, claim(s) 30-35 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19 and 22 is/are allowed.
- 6) ☒ Claim(s) 1-3, 8, 9, 16, and 36-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

1. Applicant's response to the Office Action mailed July 17, 2001 in Paper No. 14 on January 24, 2002 is acknowledged.
2. Claims 5-7, 10-15, 17, 18, 20, 21 and 23-29 have been canceled. Claims 1, 16 and 32 have been amended. Claims 36-49 have been added. Claims 1-4, 8-9, 16, 19, 22, 30-49 are pending. Claims 1-4, 8-9, 16, 19, 22 and 36-49 are under examination.
3. The following grounds of rejection are or remain applicable :

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 16 and 36-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 16 is indefinite because the claim recites that the pharmaceutical composition comprises a compound of the formula X_1 -His-Lys-X-Lys- X_2 wherein X is any amino acid, X_1 is from zero to twelve amino acids and X_2 is from zero to twelve amino acids, and it is unclear as to the effect of 1-12 additional amino acids in the positions of X_1 and X_2 on the activity of the compound versus having zero amino acids in those positions. Furthermore, it is unclear what effect any amino acid at position X will have on the activity of the claimed compound especially since the specification on page 3 states that the peptides possess anti-angiogenic activity and that it is preferred that X is a nonpolar side chain.... most preferably X is Asn, Phe or His. The dependent claims are also included in this rejection (see claims 36-49).

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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5. Claims 1-3 and 8-9 remain rejected under 35 U.S.C. 102(e) as being anticipated by Halazonetis et al. (U.S. Patent No. 6,245,886, December 4, 1997) based on a formula wherein X is any amino acid, X_1 is a fragment thereof containing at least one amino acid and X_2 is zero amino acids.

Halazonetis disclose pharmaceutical compositions of compounds and methods of using these compositions therapeutically. Halazonetis disclose the sequence contained in claim 1 where X can be any amino acid, X_1 is a fragment thereof and X_2 is zero. Halazonetis disclose in SEQ ID NO: 21 the following sequence His-Lys-Ser-Lys-Lys. Thus, the reference anticipates the claimed invention.

6. Claims 1-3, 5, 7-10 and 12-15 remain rejected under 35 U.S.C. 102(b) as being anticipated by Halazonetis et al. (WO 96/25434, August 22, 1996) based on a formula wherein X is any amino acid, X_1 is a fragment thereof containing at least one amino acid and X_2 is zero amino acids.

Halazonetis disclose pharmaceutical compositions of compounds and methods of using these compositions therapeutically. Halazonetis disclose the sequence contained in claim 1 where X can be any amino acid, X_1 is a fragment thereof and X_2 is zero. Halazonetis disclose in SEQ ID NO: 21 the following sequence His-Lys-Ser-Lys-Lys. Thus, the reference anticipates the claimed invention.

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7. Claims 1-4 and 8-9 remain rejected under 35 U.S.C. 102(b) as being anticipated by Ferreira et al. (WO 97/05258, February 13, 1997) based on a formula wherein X is any amino acid, X_1 is a fragment thereof containing at least one amino acid and X_2 is zero amino acids.

Ferreira disclose peptides for use in diagnostic and therapeutic methods. Ferreira disclose the sequence contained in claim 1 in SEQ ID NO: 113, where the sequence is Glu-Ala-Pro-His-Lys-Phe-Lys-Asn-Val which means that X is Phe (as in claims 3 and 4), X_1 is a fragment and X_2 is two amino acids. The sequence disclosed by Ferreira also meets the limitation of claim 2 which requires X_1 and X_2 to be from zero to six amino acids or zero amino acids. Thus, the limitations of the claims are met by this reference.

8. Applicant's arguments filed January 24, 2002 was not sufficient to overcome the rejections of record under 35 U.S.C. 102. Note that amended claim 16 raised new issues under 35 U.S.C. 112, second paragraph. Regarding the rejection under 35 U.S.C. 102, applicant contends that the Halazonetis reference lacks the Gly of the core sequence "Gly-His-Lys-X-Lys" recited in claim 1. Amended claim 1 recites the formula X_1 -His-Lys-X-Lys- X_2 , wherein X_1 is SEQ ID NO: 1 or a truncation fragment thereof containing at least one amino acid, X_2 is zero or SEQ ID NO: 2 (see claim 1) and X is any amino acid. Thus, the reference meets the claim limitation as the sequence recited by Halazonetis can be considered to be a truncated fragment having at least one amino acid. Applicant further states that the dependent claims are not

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anticipated as claim 1 is not anticipated, however, this statement is incorrect as the reference meets the limitations of claim 1. Applicant applies the same arguments to the rejection of record by Ferreira, stating that claim 1 requires the core residue Gly, which is incorrect as claim 1 recites alternatives to the sequence such as a fragment with at least one amino acid which is not recited as being Gly. Therefore the same arguments supplied above for the relevance of the Halazonetis reference can be applied to the rejection of record by Ferreira. Therefore, the rejections under 35 U.S.C. 102 have been maintained.

Conclusion

9. Claims 19 and 22 are free of the prior art.

10. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope Robinson whose telephone number is (703) 308-6231. The examiner can normally be reached on Monday-Friday from 9:00 am to 5:30 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S.F. Low, can be reached at (703) 308-2923.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-4242. Please affix the examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope Robinson, MS 

Patent Examiner


CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600